SUMMARY OF PUBLIC COMMENTS

Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services 12VAC35-115-10 et seq.

add statement that some listed rights may not apply to minors. I "appoint an attorney-in-fact" as an example.	 No change. Addressed in other parts of the regulations. No change. Addressed later in the regulations.
I "appoint an attorney-in-fact" as an example.	
gn with definition used by the Department of Social Services. Add examples of lt and battery.	■ Definitions of "abuse" and "neglect" are taken from Virginia Code §37.2-100.
I "neglect" to the definition of "abuse" in the same way that it is included in the ion of "exploitation."	Will provide training to assist in interpretation and application of regulatory requirements.
dd pharmacological restraints in this definition.	
rify Part 7. Providers are rarely willing to acknowledge that they are being /e.	
nsider an advance directive as presumptively controlling absent an emergency.	■ No change. Refer to the Health Care Decisions Act.
rify with regard to the statement that "an authorization must be voluntary" ularly with regard to criminal justice system practices.	■ Not needed. Regulations do not apply to the criminal justice system.
ange " <u>may</u> " to " <u>shall</u> " have decision making authority for "legal guardians, ey's in fact, or health care agents…"	■ Not necessary. Authority is granted in Virginia Code §54.1-2983.
ude legal guardians in the definition.	■ Legal guardians are mentioned and considered as part of the definition.
arify the reference in the second sentence, referring to authority of authorized sentative (AR) being "specific to designating provider,"	■ The authority of an AR is recognized only by the specific provider that designated the AR. Further clarification is provided in 12VAC 35-115-146.
arify the role of a friend or of an AR when the consumer has the capacity to give nt and add provisions that govern the role of ARs.	■ Not necessary. Clarification is provided in 12 VAC35-115-145, 146 and 70. Provisions to govern ARs are not included in the definition.
ill lid do rive no riu ae	"neglect" to the definition of "abuse" in the same way that it is included in the on of "exploitation." If plant 7. Providers are rarely willing to acknowledge that they are being e. Insider an advance directive as presumptively controlling absent an emergency. If with regard to the statement that "an authorization must be voluntary" alarly with regard to criminal justice system practices. In ge "may" to "shall" have decision making authority for "legal guardians, by's in fact, or health care agents" In ge legal guardians in the definition. If the reference in the second sentence, referring to authority of authorized entative (AR) being "specific to designating provider," If the role of a friend or of an AR when the consumer has the capacity to give

Section	Comment	Agency Response
"Authorized representative" (continued)	 Add "or persons and microboards duly incorporated under the laws of the Commonwealth, or circles of support…" Add …on behalf of an individual represented at the end of the definition. Requests that the term "legally" authorized representative be retained. 	 No change. Anyone who meets the requirements in 12 VAC 35-115-146 and relevant sections of the Code of Virginia may serve as an AR. Determination is made on a case-by-case basis. No change. This definition and terminology responds to the recommendations of a broad stakeholder group (H3R Advisory Committee) that concluded that the term "legally authorized representative" was confusing to constituents.
"Behavior management"	■ Change "management" to "support" or "intervention". Behavioral management supports" means those principles and methods employed by a provider to help an individual receiving services to achieve a positive outcome and to address and correct inappropriate challenging behavior in a constructive and safe manner in accordance with current best practice manuals and professional standards for positive behavioral supports.	■ Changed to "behavioral intervention." ■ Changed "inappropriate" to "challenging."
"Behavioral treatment plan"	 Change "serious" to "challenging or unwanted" behaviors." Clarify "systematic" data collection. Eliminate this definition replace with a definition of "positive behavioral supports." 	 Changed to "challenging behavior" and added "systematic." No change.
"Circle of support"	■ Add new definition: "Circle of Support" means a group of 3 of more people who have been designated by the individual with a disability to assist him or her to accomplish personal life goals and to support the individual in making decisions and, if so designated, act as a substitute decision-maker.	■ No change. The term is not used in the regulations. Language has been added to support this concept.
"Community services board"	■ Change "consumer" to "individual" ■ Clarify whether the "CSB" refers to the board or staff. Suggests that the citizens' board be referred to as a "board" and the service provider be referred to as an "agency."	 Changed "consumer" to "individual". Clarified the definition of "governing body".
"Complaint"	■ Retain current language. Consumers should not have to know that a specific human right has been violated to make an allegation. Under "consent" the regulations allow for the expression of consent in any manner that is appropriate to the person's communication skills. The same should apply to a "complaint."	■ No change. Consumers do not have to know that a specific regulatory provision or human right has been violated to make a complaint.

Section	Comment	Agency Response
"Consent"	■ Move the paragraph that begins "Consent should be given freely" to Section 70 with other consent provisions because it is a substantive qualification placed on consent rather simply an element of the definition.	■ No change. The H3R Advisory Committee recommended the revised definition.
	■ Change as follows: "Consent" means the voluntary and expressed agreement of an individual or that individual's legally authorized representative if the individual has one given freely and without undue inducement, any element of force, fraud, deceit, or duress, or any form of constraint or coercion—to specific services. Consent may be expressed through any means appropriate for the individual, including verbally, through physical gestures or behaviors, in Braille, through er American Sign Language, in writing, or through other methods."	
"Director"	Revise to allow appropriate flexibility to account for the hierarchy of executive leadership in hospitals and health systems.	■ Change made.
"Disclosure"	■ Delete "by a provider".	■ Change made.
"Emergency"	■ Include psychiatric emergency " or when a delay in treatment might adversely affect the recovery of an individual."	■ No change. Would expand the scope beyond the intent of these regulations.
	Retain the phase " or to avoid substantial property damage".	■ No change. Phrase is redundant.
"Governing body"	■ Clarify definition. Change "who have " to "with."	■ Changes made.
	Add language clarifying the definition of CSB governing body.	
"Habilitation"	■ Change as follows: "Habilitation refers to means the provision of individualized services conforming to professionally acceptable practices, that enhance the strengths of, teach functional skills to, or reduce or eliminate problematic challenging behaviors of an individual receiving services in a manner that These services occur in an environment that suits the individual's needs, responds to his preferences, and promotes social interaction and appropriate adaptive and communicative behaviors. In order to be considered sound and therapeutic, habilitation must conform to current acceptable professional practice." -	■ Change made.
"Human research"	■ Add "professional" as follows "… <u>or contribute to generalized professional knowledge."</u>	■ No change.

Section	Comment	Agency Response
"Individualized service plan" or "ISP"	■ Change definition as follows: "Individualized services plan (ISP) means a comprehensive and regularly updated written plan that includes but is not limited to an individual's treatment plan, functional plan, habilitation plan, or plan of care that-meets the needs and preferences of an individual and describes the measurable goals, objectives and expected outcomes."	■ Revised to reflect intent of the comment.
	Specify the interval at which the ISP should be updated, in compliance with other regulations such as Medicaid regulations, and require that the ISP is signed.	■ No change. Providers are subject to various regulatory and accreditation bodies with differing update requirements. Consumer participation requirements are found in 12 VAC 35-115-70.
"Informed Consent"	■ Objects to use of "informed" because as applied in hospitals, it requires physician communication with the patient or decision-maker. This is not a requirement in these regulations. Additionally, the definitions and Section 70 are duplicative; elements of consent and other consent requirements should be addressed in the body of the regulation and not in the definitions.	■ No change. The definition of informed consent was recommended by the H3R Advisory Committee.
	■ Should clearly specify what will be considered a "psychotropic medication."	■ No change. The definition states that this provision applies to "any [other] treatment or service that poses a risk of harm greater than that ordinarily encountered in daily life."
	■ Include an exception to these consent requirements for such medications prescribed and administered prior to admission.	■ No change. This would put the consumer and provider at risk.
	■ Why are psychotropic medications are "singled out" in the definition?	■ These medications often pose risks that are greater than those encountered in everyday life.
	Add specific components of the process for obtaining informed consent, as part of the definition.	■ No change. Substantive provisions should not be included in a definition.
	 Add "authorization to disclose PHI" as example of things that require informed consent. 	Not necessary. Covered in the definition of "authorization."
	■ For minors, consent should be obtained from the guardian	■ No change.
"Investigating authority"	■ Change to mean any person or entity with the legal authority and independent responsibility to conduct investigations of abuse and neglect. #hat is approved by the provider to conduct investigations of abuse and neglect.	■ No change. Refers to <u>internal</u> investigations. Other entities have "legal authority" to investigate pursuant to other laws…DSS, police etc.
	■ Clarify "approved by the provider to conduct <i>internal</i> investigations of abuse"	■ No change. Will address though training or
	■ The investigating authority should be trained not just approved.	consultation.
"Licensed professional"	■ Eliminate the definition to avoid confusion with additional licensed practitioners (RNs, nurse practitioners and others) that have responsibility for patient care in inpatient settings.	■ No change. Used in 12 VAC 335-115-50.
	Add "and any other professional licensed or certified by the Commonwealth of Virginia."	■ No change. Definition applies to these regulations only.

Section	Comment	Agency Response
"Local Human Rights Committee" or "LHRC"	■ Change to mean: "a group of at least five people who are appointed by the State Human Rights Committee to monitor and address human rights issues in a specified jurisdiction. See 12VAC35-115-250 D for membership and duties"	■ No change.
"Microboard"	■ Add a definition of "microboard"	■ Not necessary. This term is not used in the regulation.
"Neglect"	■ Acknowledge the controlling role of the Health Care Decisions Act (§ 54.1-2986) with respect to "withholding or withdrawing a specific medical treatment or course of treatment" when the requirements of the act are met.	■ No change. The definition is consistent with the Virginia Code.
	Revise to " <u>a person or persons</u> , and "welfare of a person <u>an individual."</u>	
"Next friend"	■ Change to "means a person whom a provider may appoint designated by a director in accordance with"	■ Change made.
"Peer on peer harm"	Inclusion of "verbal expression" in the definition adds uncertainty and judgment as "harm" is not precisely defined.	■ Definition has been revised.
	■ No definition of "harm."	
	An incident should be reported only if it results in a serious injury.	
	■ Suggests revisions "that results in harm to the individual or his property. Harm includes hitting and or threatening behavior by an individual who has with the means to carry out the threat"	
	■ Harm should not be limited to hitting or threatening; tripping, pushing, etc. could all also cause harm.	
"Person-centered planning"	■ Add the following: "Person-centered planning means a process-oriented approach which focuses planning on the needs of the individual with a disability, puts the individual in charge of defining the direction for their lives, and does not base planning on system needs or services that may or may not be available to them."	■ Added a definition of "person centered."
"Positive behavioral. supports"	■ Add a definition of <u>"positive behavioral supports.</u>	■ Not necessary. Term is not used in the text of the regulations.
"Program rules"	■ If program rules are included in a policy, the policies must be available to the consumers and the public.	■ Change made.

Section	Comment	Agency Response
"Provider"	■ Expand to include other health care providers.	■ Not necessary. Regulations are applicable only to the providers included in the definition.
"Research review committee"	■ Revise to state: "Research review committee or institutional review board means a committee of professionals <u>that to provides</u> complete and adequate review of research <u>activities in order to safeguard the rights and welfare of participants in human research. The committee shall be sufficiently qualified through maturity, experience, <u>training</u>, and</u>	■ No change. Language consistent with agency regulations on human research 12 VAC 35-180-10 et.seq.
"Restriction"	■ Clarify with regard to doctor's orders (i.e. limiting cigarettes due to health issues). Also, clarify the role of the local human rights committee in reviewing doctor's orders.	■ These regulations have no authority to limit, restrict or oversee the prescribing practices of physicians that are granted by Code or by other regulations.
"Restraint"	■ Change "medication" to "psychotropic medication for behavioral purposes"	■ Not necessary or appropriate. Any medication that has the effect of immobilizing an individual or a portion of his body can be used as a restraint.
	■ Restraints are used in an emergency. Clarify how this relates to behavioral plans when the intervention is used prior to the person being out of control.	■ When a restraint or time-out is used in a behavioral treatment plan it must be based on a detailed and systematic analysis of the behavior that clearly identifies the antecedents to the behavior so that staff may act before injury occurs.
	Is it considered a restraint when a doctor prescribes medications before an appointment.	■ It is difficult to respond to this question without further information. If the physician prescribes medication to immobilize the individual before an appointment for a medical procedure and this medication is not the generally accepted practice, it is considered a restraint. For example, if a patient is given a drug to cause drowsiness before a dental appointment it would be considered a restraint, unless the patient gives consent for the use of the drug.
	■ Are protective devices for physical deficits really restraints?	■ A device is a restraint when it restricts the freedom of movement of the individual and it is an adaptive device if it enables an individual to engage in normal activities. A wheelchair is a restraint for an individual who is capable of walking but not a restraint for an individual who is non-ambulatory and needs the chair to move normally.

Section	Comment	Agency Response
"Restraint" (continued)	■ Revise as follows: "Behavoral purposes means using a physical hold, psychotropic medication, or mechanical device to control behavior or involuntarily restrict the freedom of movement of an individual in an instance when all one of the following conditions are met: (i) there is an emergency; (ii) nonphysical interventions are not viable; and (iii) when safety issues require an immediate response."	■ "Psychotropic" removed. No other change. There are often emergency situations that can be addressed by nonphysical interventions or when there are no safety issues that require an immediate response. It would be a violation to the individual's rights to seclude or restrain him under such circumstances.
	■ Add or clarify to cover 'Standard Medical Immobilization' practices that are excluded	■ Language added in 12VAC 35-115-110 B.
	from the restraint definition in Departmental Instruction 213.	■ Deleted "hands on approaches that occur for brief
	■ Eliminate the statement: "Physical restraint does not include the use" and the accompanying qualifiers stipulated in (a) and (b).	periods" because some providers define "brief periods" as 60 seconds, one minute, and even 5 minute durations. A restraint is always a restraint. At the same
	Reinstate provisions regarding "hands on" approaches.	durations. A restraint is always a restraint. At the same time, there are brief instances of holding that are not true restraint, such as holding a child's hand while crossing a street, physically separating two adolescents who are fighting (without continuing to hold them once separated), or holding a crying child to comfort the child. The regulations now allow providers to use judgment to determine if such brief instances of holding are restraint rather than assigning some arbitrary time limit on what is or is not restraint.
	"Mechanical restraint" is defined differently here from its definition under the "restraint" definition.	Unable to respond to this commenter. There is no other definition of restraint the text of the regulations.
	■ The first sentence is included in the definition should be included in the body of regulation in Section 110.	No change. All of the information is definitional and not procedural.
	Revise "portion of his body and that does not allow when the individual does not have the option to remove the device.	■ Change made.
	■ Revise as follows: "the use of an approved mechanical device, <u>medication</u> , physical intervention or hands-on hold , or pharmacological agent to involuntarily prevent an individual receiving services from moving his body to engage in a behavior that places him or others at <u>imminent</u> risk of harm <u>and to de-escalate a dangerous situation</u>.	■ No change. Restraint should not be used as a de- escalation technique. De-escalation techniques are non-physical and non-chemical interventions to prevent an emergency. Inserted "imminent" in response to this comment.
	■ Suggests adding " body when that individual's behavior places him or others at imminent riskto each type of restraint."	■ Change made.
	■ This section is guidance rather than definition. Move to 12VAC35-115-110.	■ No change. Language is definitional and intended to clearly distinguish between the various purposes for the use of restraint

Section	Comment	Agency Response
"Restraint" (continued)	■ Concerned about "means the use of an approved mechanical device" All three definitions should be written similarly and without regard to "approved" or not. The section governing use of restraint is the proper place to specify that the device, medicine or technique must be approved.	■ Deleted the word "approved."
	■ Clarify "that cannot be removed by the individual" Would a helmet be considered a passive restraint? In many cases the individual has the ability to remove it.	■ No change. Any time an individual has the option to remove a device it is not considered a restraint. A restraint refers to the effects of the use of a physical hold, medication, or device on an individual and not on the type of holding, the type of medication or the type of device.
"Seclusion"	■ Sometimes seclusion is interpreted to apply to situations where an individuals egress from home or work is prevented for health and safety reasons or to maintain the person on his work environment. Is that seclusion?	■ Seclusion is more than confining an individual in a given setting. Seclusion is isolating the individual from others and from normally stimulating activities in an area from which egress is prevented. Egress alone does not define seclusion
	■ How is seclusion is carried out by "verbal means" when there is a locked or secured door? These concepts seem inconsistent.	■ An individual who is prevented from leaving an isolated room or area by staff's verbal threats is technically secluded. Egress also may be prevented by a locked or secured door. No change needed.
"Serious injury"	 Clarify and add limits to specify that professional ongoing care by a licensed physician is required past initial diagnosis. This would address incidents now required to report such as bee stings, scrapes etc. States that the definition should be aligned with the licensing regulations. 	■ Not needed. The H3R Advisory Committee did not recommend changes. This definition was not revised in the proposed regulations.
"Services"	■ Suggests adding "assessment" after "SA"	Revised to cover the scope of the regulation.
"Services record	 Add "that" after " information" Acknowledge that electronic records also a part of the services record. 	■ Changes made for clarity.
"Time out"	■ Time-out from positive reinforcement is a basic principle in the practice of applied behavior analysis. This clinical term refers to a continuum of procedures by which an individual's access to positive reinforcers is systematically interrupted contingent upon the occurrence of a target behavior. Past versions of Virginia's Human Rights regulations have recognized the importance of the procedure and permitted its use in all forms in the training centers. The current draft does not include the more restrictive form of time-out from positive reinforcement known as 'locked time-out', 'isolated time-out', 'time-out room', or 'secure time-out'.	■ No change. Although there are technical differences between the various types of time out that are recognized in the professional literature and even in federal regulations, these regulations are intended to create greater safeguards for the human rights of consumers. Although secure time-out, isolated time-out or other forms of time out that place the consumer in a location away from positive reinforcement and from which egress is prevented are professionally

Section	Comment	Agency Response
"Time out" (continued)	Recommends the following paragraphs to expand the time-out definition in the revised regulations. Time-Out from Positive Reinforcement: The withdrawal of the opportunity to earm positive reinforcement or the loss of access to potential reinforcers for a specified period of time contingent upon the occurrence of a behavior. Two forms of "time-out from positive reinforcement" are defined below and are subject to restrictions in these regulations. 1. 1 "Time-out" means the involuntary removal of an individual by a staff person from a source of reinforcement to a different, open location for a specified period of time or until the problem behavior has subsided to discontinue or reduce the frequency of problematic behavior. 2. "Secure time-out" means the involuntary relocation of an individual to a room from which egress is prevented by a door secured with a mechanism that requires continuous staff contact to remain engaged in order to limit access to sources of reinforcement for a specified behavior. ■ "Time out" is not clear. "Involuntary removal" is particularly unclear. ■ Indicates that if staff members physically move the client to a time out area, the movement would constitute a physical restraint rather than time out. ■ Believes there should be differentiation between time out that is used to address a challenging behavior when less restrictive alternatives have failed and time out that is used by the individual as a strategy to self calm or reduce stress: "Time out" means assisting an individual to regain emotional control by removing the individual from his immediate environment to a different, open location until he is calm or the problem behavior has subsided (1) the involuntary removal of an individual by a staff person from a situation or location source of reinforcement to a different, open location for a specified period of time or until the problem behavior has subsided for the purpose of discontinuing or reduceing the frequency of future challenging problematic behavior; or (2) the voluntary	 ■ The involuntary removal may be physical, in which case it would be a restraint but it may also be in the form of a verbal order or threat by a staff person. ■ See explanation above. ■ Time-out can be both involuntary and voluntary. There is no need to regulate a voluntary activity. These regulations are intended to safeguard an individual's human rights and do not address procedures, such as voluntarily going to a quiet place to self calm or reduce stress that have no potential to violate those rights. No change has been made in response to the comment.
"Treatment"	■ Suggests changing "sound" to "clinically appropriate"	Revised to cover the scope of the regulation.
12 VAC-35-115-40 Assurance of Rights	B. Delete requirement that providers give notice at the time an individual begins service and every year thereafter.	B. No change. Individuals should receive notice of their rights at least annually. This standard is also consistent with other requirements for notification (HIPAA).

Section	Comment	Agency Response
12 VAC-35-115-40 Assurance of Rights	■ Require the written notice of rights to be in alternate format and languages to ensure communication is effective for those who receive and request such notice.	Revised for clarification.
(continued)	■ Add: The notice shall tell an individual the <u>name and telephone number of the current</u> human rights advocate, how he can contact the human rights advocate and give a short description of the human rights advocate's role.	
	■ Suggests changes "the provider shall give a written notice to the individual at the time services begin and every year thereafter."	■ Change made.
	■ Revise to ensure that the notice of human rights have been discussed with the individual.	
	■ Add a requirement that the Department work with CSBs to develop a standardized curriculum to train persons on how to conduct an investigation.	■ Will address in training or consultation.
	■ The signed notice in the record does not help the consumerit holds no valuemakes it hard to move to an electronic recordsuggest documenting the that the rights were reviewed with the individual in the progress notes.	■ No change
	D . Require the human rights advocate to assist an individual identify and pursue other rights and remedies that may be available and he may be entitled to under federal or state law, such as the Center for Medicaid and Medicare Services, the Social Security Administration, or the fair housing board of Virginia.	D. No change.
12 VAC 35-115-50	A, Recommends retaining <u>"receiving services"</u> in the provision.	A. No change.
Dignity	B.1. <u>Use of Preferred Legal Name</u> — ■ Requests clarification of the meaning of preferred legal name. Some may not be appropriate for treatment settings. Indicates that review of the restriction appears to be excessive. Questions whether the restriction requires review by the local human rights committee (LHRC) or is part of program rules.	B.1 . A preferred name is what a person wants to be called. Providers can use of a name in accordance with the provisions in this section of the regulations. This does not require review by the LHRC. The restriction may be applied on a case-by-case basis depending on the circumstances. There may be a general statement included in program rules.
	■ Providers should not be required to take the steps listed in this section to limit the use of a legal name.	■ No change.
	■ Require a licensed professional to discuss limits on the use of the preferred legal name and explore acceptable alternatives with the individual who is being restricted.	■ No change.
	■ The requirement that a licensed professional can restrict dignity rights is not a high enough standard.	No change. This standard was recommended by the H3R Advisory Committee.
	■ Should document all reasons to restrict a dignity right.	■ No change.

Section	Comment	Agency Response
12 VAC 35-115-50	B.2. Be protected from harm	B.2 No change. The concept of "harm" depends on the individual. Harm must be determined on a case-by-
Dignity	■ The use of "harm" is too broad. "Harm" should be clarified in the definitions section. States "the harm should be greater than that which occurs in everyday life…"	case basis.
(continued)	B.4. <u>Have opportunities to communicate</u>	D. A. No observe
	■ Too restrictive. Consumers, like anyone else, should have the right to privacy when communicating with anyone.	B. 4. No change.
	B.5. Be provided with general information	B.5. Change made.
	■ Suggests inserting "given a written copy of general information about program services, policies, and rules in a manner easily understood by the individual."	
	B: Insert new provisions in subsection B	
	1. Receive services in an environment that: meets the individual's needs; responds to his preferences; is person-centered and directed; and promotes participation in community and social activities that enhance personal growth and full community participation to the maximum extent.	1. Change made in 12 VAC 35-115-50 A
	7. Exercise maximum self-determination regarding daily routines, such as	7. No change.
	bedtime and meals, social relationships and other activities, consistent with sound therapeutic practices, the individual's ISP, and applicable laws and regulations.	
	C. Several commenters suggested the following revisions:	
	2. Receive a nutritionally adequate, varied, and appetizing <u>meals that are diet</u> prepared and served under sanitary condition, served at appropriate times and temperatures, <u>and</u> consistent with any individualized diet program <u>and the individual's preferences</u> , including cultural and religious preferences as they affect diet.	2. Changes made.
	3. Live in a	

Participation in religious services or practices may be reasonably limited by the provider if such participation is inconsistent with the individual's ISP or significantly affects the activities of others in a demonstrated negative manner. Any restriction on religious activity participation shall be documented and	4. No change.
include justification for such restriction.	4. No change.
4. Practice a religion and participate in religious services subject to their availability, provided that such services are not dangerous to the individual or others and do not unreasonably infringe on the freedom of others.	
5. Have paper, pencil and stamps provided free of charge for at least one letter every day upon request, <u>if an individual does not have adequate personal funds</u> . <u>If an individual has funds for clothing and to buy paper, pencils, and stamps to send a letter every day the provider does not have to pay for them.</u>	5. Changes made for clarity.
6. Have Communicate privately with any person by mail, or e-mail if the individual has access to a computer, and have help in writing or reading mail as needed.	6. No change.
Insert "email" into the provisions that refer to "mail."	
In 6.a. insert "or designee."	6.a. Change made.
6.a. Suggests inserting language to require that the director discuss any limitations imposed on mail access with the individual.	6.a. Changed to require that mail limitations are discussed with the individual.
In 6.b. the basis for restricting mail contact "is too limited." Concerned that this restriction may not be invoked in potentially dangerous circumstances.	6.b. Issue addressed in subsection 6.a. of this section.
6. b. The standard "demonstrable harm to the individual's mental health" as the basis for limiting mail "is so broad that almost anything would be covered"	6.b. No change. Standard can be applied on a case-by-case basis depending on individual circumstances.
In 6.c add "professional staff" after treatment team.	6.c. Clarifying change made to sections 6, 7, and 8.
6.c. This section seems to contradict the idea that consumers have all of their rights and is also contrary to recovery, empowerment and self-determination. When a restriction is necessary it should be discussed with the consumer in order to reach a compromise. There also should be a means to appeal the decision to restrict.	6.c. No change. A consumer can file a human rights complaint any time he believes his rights under these regulations have been violated.
7.c.(1) This provision is too restrictive. Restrictions should not require LHRC review.	7.c.(1) No change The process and steps for imposing the limitations has been recommended by the H3R
7.c.(1) Proposes requiring a response within five working days from the LHRC and the human rights advocate	Advisory Committee .
7 and 8 Should not require LHRC approval of phone and visitor restrictions in residential substance abuse programs. Should only require the program to inform the human rights advocate of the restriction.	7 and 8 See above response to 7.c.(1).
	provided that such services are not dangerous to the individual or others and do not unreasonably infringe on the freedom of others. 5. Have paper, pencil and stamps provided free of charge for at least one letter every day upon request, if an individual does not have adequate personal funds. If an individual has funds for clothing and to buy paper, pencils, and stamps to send a letter every day, the provider does not have to pay for them. 6. Have Communicate privately with any person by mail, or e-mail if the individual has access to a computer, and have help in writing or reading mail as needed. Insert "email" into the provisions that refer to "mail." In 6.a. insert "or designee." 6.a. Suggests inserting language to require that the director discuss any limitations imposed on mail access with the individual. In 6.b. the basis for restricting mail contact "is too limited." Concerned that this restriction may not be invoked in potentially dangerous circumstances. 6. b. The standard "demonstrable harm to the individual's mental health" as the basis for limiting mail "is so broad that almost anything would be covered" In 6.c add "professional staff" after treatment team. 6.c. This section seems to contradict the idea that consumers have all of their rights and is also contrary to recovery, empowerment and self-determination. When a restriction is necessary it should be discussed with the consumer in order to reach a compromise. There also should be a means to appeal the decision to restrict. 7.c.(1) This provision is too restrictive. Restrictions should not require LHRC review. 7.c.(1) Proposes requiring a response within five working days from the LHRC and the human rights advocate 7 and 8 Should not require LHRC approval of phone and visitor restrictions in residential substance abuse programs. Should only require the program to inform the

Section	Comment	Agency Response
12 VAC 35-115-50 Dignity (continued)	8. Questions the role of the LHRC in this provision. Recommends that the exceptions for substance abuse programs should apply to mental health programs.	8. No changes. These provisions were recommended by the H3R Advisory Committee. The agency intends to provide training to providers and staff in the
(conunaca)	8.a. Inserting the word "only" as emphasis on visitor restriction.	application of these regulations.
	8.a. Concerned that "harm" is used without a working definition in this provision. Believes that consumers should be able to have visitors unless there is some legal reason to restrict them.	8.a. Change made.8.a. No change.
	D. The provider's duties	D. The provider's duties
	Several commenters suggested revisions:	No change is needed. Each circumstance involving
	1. Regarding minors' preferences, in referencing "the parent" this creates ambiguity about which parent. Custodial? The one who signed for the individual? Both? What if the parent is not the care taker or custodian?	minors is considered on a case-by-case basis.
	3.a. Remove <u>"employment"</u> or <u>"volunteering"</u>	3.a, 3.b, 3c , and 3.f. No changes.
	3.b. Insert in the last sentence This <u>"shall"</u> include <u>"at least of"</u> the following actions <u>"and any other action as deemed appropriate."</u>	
	3.c. AddIn the case of incidents of peer-to-peer harm, protect the individuals from the aggressor in accordance with sound therapeutic practice and these regulations.	
	3.c.It is not always practical to notify the advocate within 24-hours.	
	3.d Clarify that no punishment or retaliation applies to reports made by staff in "good faith."	
	3.f. AddThe investigation shall be conducted by an impartial independent investigator person with training and experience in the knowledge, skills, and abilities necessary to conduct effective investigations and who is not involved in the issues under investigation or an employee of the provider.	
	3.e.4 and 5 Add language such as If needed, the decision shall be provided to the individual in alternate format and/or explained in the mode of communication or language most effective for the individual." or This process shall be clearly explained in the mode of communication and language most appropriate to the individual's functional abilities.	3.e.4 and 5. Changed sections 3.e.4 and 5 in response to the comment.
	3.e. The state should offer training for investigators.	3.e. No change. Will address through training or consultation.

Section	Comment	Agency Response
Section 12 VAC-35-115-60 Services	B. The providers duties 4.d. Provision is not clear. What is meant by "approval of seclusion and restraint" 5. With regard to the parent's preferences Would it be better to state "a parent?" Should also be an exception to this requirement for those minors who seek services without the knowledge or permission of a parent. 7. Change wherever it appears in this document "With the individual er and,if applicable, the authorized representative's consent" And, "When the individual er and,if applicable, his authorized representative requests " The use of the conjunction "or" implies that the individual does not need to be involved in planning services, giving consent, or participating to the degree he is able in decisions about his life. 7. Changeproviders "may" toproviders "shall" involve family members in services and discharge planning. 8. Change Providers shall ensure that the entries in an individual's services record are at all times authentic, accurate, complete, timely, and pertinent, and meet professional standards. ■ Proposes the addition of the following: i) With the exception of emergency situations or unforeseen circumstances outside of the provider's control, the scheduled medical, mental health appointments shall not be cancelled. ii) If an unforeseen circumstance or emergency requires cancellation of a scheduled	 Agency Response 4.d. Change made for consistency. 5. No change. 7. No change. This should be an option rather than a requirement. 8. No change. No change.
12 VAC 35-115-70 Participation in Decision Making and consent	appointment, the cancellation and its justification shall be documented in the individual's record, and the appointment shall be rescheduled immediately. A.1.a. The individualized service plan (ISP) should also include goals, strengths and natural supportsthe plan belongs to the individual not the provider. A.1.b. Include a reference to "authorized representative" as in Section A.1.c to account for individuals who lack capacity to participate in such planning. A.2.(a) subsections 1-8. Should eliminate sections115-70 (A) 2(a) (1-8) from this section since they are included in the definition. The qualifications regarding informed consent are integral to the concept of consent being "informed" and therefore should remain a part of the definition. A.2. Change "surgery" to "surgical procedures."	 A.1.a. Revisions made to the definition of ISP. A.1.b. No change. Revision made to 12 Vac 35-115-A 1.c. A.2.(a) subsections 1-8. No change. A.2. Change made.

Section	Comment	Agency Response
12 VAC 35-115-70 Participation in Decision	A.2.b. Suggests the following: Evidence of informed consent shall be documented in an individual's services record and indicated by the signature of the individual or his authorized representative on a designated form er and the ISP.	A.2.b No change.
Making and consent (continued)	A.2.c.(1) (a) and (b) Add a statement of the risks and benefits of the procedures to	A.2.c.(1) (a) and (b) No change.
(continued)	these provisions.	A.2.c.(2) Change "separate" to "new."
	A.2.c.(2) Change "separate" to "distinct."	
	A.2.c(3) Proposes changes: Providers shall inform the individual receiving services or his authorized representative that: the individual may obtain a second opinion before receiving electroconvulsive treatment; and the individual is free to refuse consent or later add (4) For any individual under age 18 years ,	A.2.c(3) No change.
	A.3. Add "has been determined" after "where the individual"	A.3. Change made.
	A.3.a . This provision establishing review rights and processes for objecting individuals who do not have decision-making capacity and have authorized representatives, will disrupt treatment in acute care hospitals. If any such individual can appeal decisions of his authorized representative to the LHRC, the appeal likely will exceed the patient's length of stay given an average acute care hospital stay of 4-5 days. Further, prohibiting the hospital from initiating treatment in this situation will force the hospital to deny treatment that has been approved by a legally authorized surrogate decision-maker; such denial of treatment puts the hospital in a difficult position legally, possibly subjecting the hospital to liability for failure to provide the authorized treatment. Suggest that this provision not apply to acute care hospitals given the nature of acute hospital services as compared to services provided in other regulated mental health programs.	A.3.a. No change.
	A.3.a. Concerned that the interpretation of the term "authorized representative" is broadened to include any number of legal instruments, including Medical Powers of Attorney. In some cases, an individual may have assigned an authorized representative, but have capacity to provide informed consent. Should the regulations permit the provider to simply follow the individual's directions rather than require a hearing.	A3.a. No change.
	B.1. Legal guardians should be included in decision-making when an individual is not capable of making his own decisions.	B.1. No change.
	B.2. Add: "shall honor these preferences unless contraindicated in the individual's ISP" at the end of the sentence.	B.2 No change. This language is too restrictive.
	B.4. Provisions should reference competent minors consenting to treatment. Does this mean that when the parent is involved, that both the parent and minor must consent when required, or is just the minor's consent is adequate.	B.4. No change.

Section	Comment	Agency Response
12 VAC 35-115-70	B. 6. Suggests changes: In the event that the treatment lasts more than 24 hours, the provider shall. Providers shall obtain	B.6. No change.
Participation in Decision Making and consent	B. 8. Cite the referenced statute for clarification.	B. 8. No change. Deleted reference to statute.
(continued)	B.8.c. Proposes the following revision: If an individual certified for admission to a state Training Center under § 37.2-806 of the <i>Code of Virginia</i> requests discharge, the director, or designee , shall contact the individual's Community Services Board to initiate discharge planning. shall determine whether the individual continues to meet the criteria for admission. If the director denies the request for discharge, the individual and the individual's authorized representative shall be notified in writing of the reasons for the denial and of the individual's right to seek relief in the courts. The request and the reasons for denial shall be included in the individual's services record.	B.8.c . Changes made to clarify this section.
	Add the following:	
	■ Providers shall provide Program Rules to individuals in writing, or in alternative form of communication appropriate to the individual's needs and explained to the individual in a manner that will ensure that they understand the expectations placed upon them. Alternative formats and modes of communication include but are not limited to large print, Braille, picture communication, American Sign language, writing, or other methods.	■ No change.
	■ Providers shall make available information, or access to information, about inclusive recreational, civic, and social activities or resources available in the community; and shall promote, to the extent appropriate to the individual's ISP and services, the individual's participation in community life.	■ No change.
	■ Should be a notice for discharge and transfers in case an individual wishes to appeal.	■ No change.
12 VAC 35-115-80	A. Clarify why "federal" is deleted.	A. Not needed.
Confidentiality and authorization to disclose information	B.2. Clarify requirements for release of information to other health care providers involved in an individual's treatment. The regulations restrict the release of information without authorization to providers who are licensed, operated or funded by the Department. Expand the definition of provider to include other health care providers.	B.2. No change. Permits disclosure of information for treatment, payment or health care operations to any person or persons the extent required or permitted by state law.
	B.2.a Clarify: "The name of the organization and the name or other specific identification of the person or persons or class of persons to whom the disclosure is made." Proposes that the regulations be written such that the name of the organization to whom the disclosure will be made will be sufficient.	B.2.a. No change. Requires an individual to be specific about the information that can be disclosed when signing an authorization for release of information in a medical record.
	B.2.b Clarify: "an indication whether the authorization extends to the information placed in the individual's record after the authorization was given but before it expires."	B.2.b. No change. The person completing the authorization must specify whether the authorization applies to the information currently in the record on the

Section	Comment	Agency Response
12 VAC 35-115-80 Confidentiality and	Should delete requirement.	day it is signed or whether it authorizes information that is subsequently added to the record.
authorization to disclose information (continued)	B.2.d Clarify "If the authorization is signed by an authorized representative a description of the authorized representative's authority to act."	B.2.d. No change. Requires a general response such as "legal guardian" or "authorized representative under the Human Rights Regulations." Does not require a specific code citation.
	B.3. Clarify the reference to the Virginia Government Data Collection and Dissemination Practice Act. Implies that it gives an individual the right to object to disclosure and have those objections addressed.	B.3. Reference deleted.
	B.8. Delete B.8. because it repeats the provisions in B.2.	B.8. No change.
	B.8.h. Add an exception to allow reports to be submitted to the Department of Social Services.	B.8.h. No change. Disclosure to the Department of Social Services is allowed under these regulations.
	B.8.j. Clarify the agency intended to eliminate reporting threats to "the public." Indicates that the regulations only allow reporting threats against individuals.	B.8.j. No change. Conforms to § 54.1-2400.1(B) of the Code of Virginia.
	B.9. A time period should be specified for the reporting required in this provision.	B.9 . Change made. (see 12 VAC 35-115-80 B 9.h.)
	B.12. Add "or his representative" after "individual" in this provision. This should be written more broadly to include the discretion to withhold this accounting of disclosures from anyone if there is risk of harm–including disclosures regarding threats of harm and not just abuse.	B.12. Change made.
	General comments:	
	■ Clarify whether programs that are not subject to Health Insurance Portability and Accountability Act of 1996 (HIPAA) should be required to comply with HIPAA. Will HIPAA override Family Education Rights and Privacy Act (FERPA).	■ No change. These regulations do not impact whether a provider is subject to HIPAA. A provider subject to these regulations must comply with these regulations and any other state or federal law or regulations that may be applicable to it.
	■ Psychotherapy notes should not be protected from the individual's scrutiny.	■ No change. Under both the HIPAA Privacy Rule and Virginia law an individual does not have the right to access psychotherapy notes.
12 VAC 35-115-90 Access to and amendment of services records	C.2.a. No provision is made in this phrasing for the professional judgment of a physician or psychologist to determine that access to the record may endanger the psychological or emotional safety of the individual. Physicians and psychologists treating the child should be allowed to protect their clients' emotional stability.	C.2.a. No change. The language conforms to the HIPAA privacy rule.
	■ Add "Requests to" for items A.1., A.3., C.1 and C4to indicate that consumer and authorized representative may only request to see, read, get a copy of, challenge, amend, or receive an explanation of anything in service record.	■ No change in A.1 . and C.4 . Change made to A.3 to be consistent with HIPAA.
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Section	Comment	Agency Response
12 VAC 35-115-90 Access to and amendment of services records	Authority for certain other restrictive decisions (i.e. access to record) should be standardized by placing them under the judgment of licensed professional staff.	■ No change. Determination by physician or treating clinical psychologist is required by Virginia Code § 32.1-12.71:03(F).
(continued)	■ There may be a contradiction between 12VAC35-115-80 (B).(5).(c). and 12VAC35-115-90.	■ No change. There is no contradiction. 12 VAC 35-115-80(B)(5)(c) deals with disclosure of a minor's record while 12 VAC 35-115-90 deals with access to a minor's record.
	■ Individuals should be permitted to appoint someone else to review their record.	■ No change. The regulations provide that individuals
	■ There should be a third party to review the request for an amendment. Believes that the author of the record in question should be taken out the picture if the director	may provide authorization to disclose their record to person, including another professional, for review.
	believes that the integrity of the review will be compromised.	■ No change. The provider has the option to permit someone other than the author of the record to perform the investigation.
12 VAC 35-115-100	A.1. Exceptions will have to occur for every substance abuse (SA) residential	A.1. No change.
Restrictions on freedoms of everyday life	consumer for several of freedoms included in the list. Indicates that exceptions for SA residential programs should be built into to the document related to items a, b, and f "when sound therapeutic practice requires the restriction." This authority should not be limited to initial phases of treatment. Programs often find out about dangerousness or vulnerabilities after initial phase of treatment.	·
	These same assumptions apply to some intensive residential mental health programs (e.g. crisis care) that admit persons in psychiatric crisis who require the specialized structure/supervision that such programs provide.	
	A.1. Suggests the following revisions:	
	add: "or any other public setting"	
	g. Freedom to make purchases in canteens, vending machines, or appropriate retail establishments consistent with his preference. stores selling a basic selection of food and clothing.	
	h. Freedom to determine his own activities and personal schedule to the maximum extent feasible consistent with personal preference and goals.	
	i. Freedom to fully participate in any other activities of community life, consistent with the civil and legal rights of free citizens.	
	B. 2 and B. 4 change "orderly" to "clean"	B.2. and B.4. No change.
	B.3. "Qualified professional" should be defined in the regulations.	B.3. No change.
	■ A "qualified professional" should be one "who is provider of services to the individual"	■ No change.

Section	Comment	Agency Response
12 VAC 35-115-100	B.3 a Revise " behavior, preferences, nursing and medication needs, ability to	B.3.a. No change.
Restrictions on freedoms of everyday life	function independently level of independence, and promotion of everyday life facilitation of self-determination."	B.5.d. No change.
(continued)	B.5.d. Allow for the "rules" to be "given to the individual and, if applicable, his authorized representative upon admission and at any time they are requested."	b.3.u. No change.
12 VAC 35-115-110	■ The use of involuntary seclusion, restraint and time out should be identified in the	■ No change.
Use of Seclusion, restraint and time out	regulations as an intervention of "last resort". Providers should make every effort to intervene in the least intrusive, least restrictive, dignity preserving, clinically sound manner before resorting to involuntary measures.	
	■ Regulations do not define "qualified professional. Questions whether this means "standards of practice."	■ No change. A "qualified professional" must meet standards of practice for his profession.
	■ Change all reference from "behavioral treatment" to "behavioral support."	■ No change.
	■ The restraint uses section should be relocated from the definition of "restraint" in 12 VAC 35-115-30 to a new 12 VAC 35-115-15.B entitled "Restraints used for the following behavioral, medical or protective purposes."	■ No. change.
	■ Is blocking egress from a building is considered "seclusion."	■ Seclusion is considered more than confining an individual in a given setting. Seclusion is isolating the individual from others and from normally stimulating activities in an area where egress is prevented. Egress alone does not define seclusion.
	■ Change the title of the section to "Time out for behavioral purposes."	■ No change.
	■ Will rear facing seat belts, lap trays, etc…be reviewed as part of the behavior plan. Asks whether these devices will be allowed.	■ See new section 12 VAC 35-115-110 B.
	B.1. It is inappropriate for providers to meet with the individual/authorized representative upon admission to discuss the individual's preferred interventions because the type of restraint used is a clinical decision that requires a physician's order under federal conditions of participation. Further, it is alarming and unsettling to individuals to be asked this question at admission, indicating the possibility of the use of restraints, however unlikely, at a time when they may feel frightened and vulnerable.	B.1. No change.
	B.1. There should be sufficient flexibility that the provider not be required to discuss the "preferred" interventions for an individual with no history of behavior which might require the use of a behavioral restraintIt might be more appropriate for the regulation to require the provider to provide a copy of their applicable policy and to answer any questions asked by the individual and, if applicable, his authorized representative.	B.1. No change.

Section	Comment	Agency Response
12 VAC 35-115-110	B.1. Suggests the following revision:	B.1. Change made.
Use of Seclusion, restraint and time out (continued)	Providers shall meet with the individual or his authorized representative upon admission to the service to discuss the individual's preferred interventions in the event that his behaviors or symptoms become a danger to self or others; and under what circumstances, if any, the intervention may include seclusion, restraint, or time out.	
	B.2. It is imprecise and impractical to record all known contraindications to use of restraint in the service record. This assessment should be unnecessary because contraindications to any form of treatment should already be in the record.	B.2. Revised for clarity.
	B.2. Suggests revisions:	
	Providers shall: (i) document the circumstances under which seclusion, and restraint and time out are to be used that include the individual's preferences; (ii) document all known contraindications to the use of seclusion, time out, or any form of physical or mechanical restraint, including medical contraindications and a history of trauma, in the individual's services record; and (iii) shall flag and the record shall be flagged to alert and communicate this information to staff.	
	B.3. Only residential facilities for children that are licensed under the Regulations for Providers for Mental Health, Mental Retardation and Substance Abuse Residential Services for Children (12 VAC 35-45-10 et seq.) and inpatient hospitals may use seclusion. The use of seclusion in the case of a minor shall be used only in an emergency situation and shall not be a component of a behavioral support plan.	B.3. No change.
	B.7.b. Suggests the revision:	B.7.b. Changes made.
	When using restraint or seclusion for behavioral purposes, trained qualified staff will monitor the individual's medical and mental condition continuously for the duration of the restriction.	
	B.7.d. Suggests the revision:	B.7.d. No change. Required by Code.
	Incidents of seclusion and restraint when used for behavioral purposes, are reported the department as provided in 12 VAC 35-115-230 including the rationale for and the type and duration of the restraint. B.11. Explain the purpose of the review.	B.11 . The purpose of the review, which is outlined in detail in 12 VAC 35-115-110.B.13, is to assess the continued need for the procedure, establish behavioral criteria for release, and document the rationale for use of the procedure.

Section	Comment	Agency Response
12 VAC 35-115-110	B.11 Suggests revisions:	B.11 No change.
Use of Seclusion, restraint and time out (continued)	Providers shall ensure that a qualified professional who is involved in providing services to the individual reviews every use of any behavioral restraint as soon as possible after it is carried out.	
(commuca)	B.11 Clarify "ASAP" regarding a qualified professional reviewing every use of any restraint as soon as possible after it was carried out.	B.11 Not defined.B.12 No, the time-limited approval cannot be specified
B.12 Can the time limited approval be "until calm." as "until calm." Prospecifies the maxin remain in seclusion establishes the mather the provider must establishes the maxin the provider must establishe the maxin the provider must established the maxin the provider must establishe the maxin the provider must established the maxin the maxin the maxin the provider must established the maxin the	as "until calm." Provisions in 12 VAC 115-110.B.14 specifies the maximum time that an individual may remain in seclusion or restraint. 12 VAC 115-110.B.15 establishes the maximum time for time-out. In addition, the provider must establish clear and measurable behavioral criteria that are used by staff to determine when the consumer must be released from the procedure.	
	B.12 Revise the first line as follows: Providers shall make sure that review and approval by a qualified professional for the use or continuation of restraint for behavioral purposes is documented in the individual's services record."	B.12 No change.
	B.13. Change behavioral to specific in this provision.	B.13 No change.
	B. 13 . Can the staff person who performs the restraint do the required assessment? The requirement for emergency restraint appears more appropriate for hospital rather than community programs, where there may only be a single staff person.	B.13 This should be addressed in the provider's emergency policy. There should always be back-up staff for an emergency.
	B. 13.a, b, c, d, and e. Remove "mechanical."	B.13 a, b, c, d, and e. No change.
	B.13.a The required assessment as to "why alternatives to proposed use of seclusion and mechanical restraint have not been successful" is unrealistic, especially with respect to use of medications Because seclusion and restraint are used rarely and only in emergencies, the CMS and JCAHO prerequisites imposed on hospitals (i.e. that all available alternatives be tried and found ineffective to protect the patient or others from harm) should be sufficient safeguards.	B.13.a. Changes to clarify.
	13. e. Recommends inserting "to include alternate communication formats where necessary" after "understand."	B.13.e No change.
	B.14 Remove "or seclusion" and add " to specific instances in which lesser restrictive intervention has not worked and each episode shall be limited to no longer than it takes for the individual to meet the specific criteria established for the release up to a maximum of"	B.14. No change.
	B.15. The requirement that "Providers shall limit each approval for time-out to no more than 30 minutes." is imprecise because it is not clear what is meant by an "approval".	B.15. Change made.

Section	Comment	Agency Response
12 VAC 35-115-110 Use of Seclusion, restraint and time out (continued)	B.17. Recommends changing: "Providers may use restraint or time-out in a behavioral treatment plan to address behaviors that present an immediate danger to the individual or others, but only after a qualified professional has conducted a detailed and systemic assessment analysis of the behavior and situations in which the behavior occurs".	B.17. Change made.
	B.17 Indicates that "systemic assessment" should be revised to "systematic assessment."	B.17. Change made.
	B.17. Suggests this section be revised as follows: Providers may use restraint or time-out in a positive behavioral support behavioral treatment plan to address behaviors that present an immediate danger to the individual or others, but only after a qualified professional has conducted a detailed and systemic analysis of the behavior and the situations in which the behavior occurs, functional behavioral analysis to include but not be limited to: the antecedents to the behavior, the environments, situations, and times, in which the behavior occurs, and the communicative function of the behavior and the professional has determined that safety cannot be achieved with the use of positive interventions and that no lesser restrictive alternative will be effective. This determination shall be reevaluated at least every 6 months. a. Providers shall develop any behavioral treatment support plan involving the use of restraint or time-out for behavioral purposes according to its policies and procedures, which ensure that: (1) Behavioral treatment support plans are initiated, developed, carried out, and monitored by professionals who are qualified by expertise, training, education, or credentials to do so. (2) Behavioral treatment support plans include emphasize nonrestrictive procedures and environmental modifications that (i) address the communicative function of the targeted behavior and seek to replace it with a more acceptable means of communication and (ii) the individual's preferences for interventions as identified in the ISP. (3) Behavioral treatment support plans are submitted to and approved by an independent review committee comprised of professionals with training and experience in applied behavior analysis and/or positive behavioral supports who have assessed the technical adequacy of the plan and data collection procedures.	B.17. No change.

Section	Comment	Agency Response
12 VAC 35-115-110 Use of Seclusion, restraint and time out (continued)	b. Providers shall document in the individual's services record that the lack of success, or probable success, of less restrictive procedures attempted and that the risks associated with not using restrictive procedures not treating the behavior are greater than any risks associated with the use of restraint. This documentation must reflect trials of less restrictive procedures employed within an appropriately developed, data-based positive behavioral support plan and not an assumptions that the less restrictive procedures will not work.	b. No change.
	B.17.c. Revise the process to require review of a behavioral plan by and provisional approval of the advocate prior to implementation rather than delaying this review until the LHRC is scheduled to meet. The plan would then be submitted for approval to the LHRC at its next scheduled meeting.	B.17.c. No change.
	■ Consider giving the LHRC chair the authority temporarily approve a behavioral plan.	■ Nothing in these regulations prohibits the LHRC from establishing its own procedures for granting temporary approval.
	 The required LHRC approval of behavior health plans using restraint or time out is impractical for interventions used only in emergencies (as is the rule for acute care hospitals). If this requirement is intended to apply only in certain programs, the regulations should clearly state its scope. B.17.d. Should the LHRC determine its schedule for review of behavioral treatment 	■ Hospitals <u>may</u> use seclusion or restraint or time-out in emergencies without behavioral treatment plans. However, if a provider elects to include the use of a restrictive procedure in a behavioral treatment plan, the requirements in this section of the regulations apply. No change has been made to B17.c.
	plans. Add new 12 VAC 35-115-110-B.19 to govern and allow the use of "secure time out"	B.17.d. While the regulations specifies that the LHRC must review behavioral plans quarterly, this does not prohibit a LHRC from conducting more frequent reviews if it is considered appropriate.
	in training centers in compliance with federal ICF/MR regulations maintained by the Centers for Medicaid and Medicare Services (CMS).	■ Specific provisions for "secure time out" have not been included in these regulations. There are technical differences between the various types of time-out that are recognized in the professional literature and even in federal regulations and appreciate the professional basis for these differences. However, these regulations are intended to create greater safeguards for the human rights of consumers. While secure time-out, isolated time-out or other forms of time out that place the consumer in a location away from positive reinforcement and from which egress is prevented are professionally recognized as being technically different from seclusion, the experiences of consumers in both are the same.

Section	Comment	Agency Response
12 VAC 35-115-120 Work	B. The term "consumer" should be changed to "individual" for consistency.	B. "Consumer" deleted.
12 VAC 35-115-130 Research	■ Recommends some impartial, routine oversight of the research projects that allows the individual to share candidly and frankly of the benefit, preferences and concerns about the research.	■ No change. The LHRC could, of its own accord, oblige the provider to comply with this type of oversight.
	B. Suggests that the provisions be revised as follows: 3. Providers shall obtain review and approval from an institutional review board (IRB)or research review committee prior to performing or participating in a human research protocol. Documentation of this review and approval must be maintained and made available upon request by the individual or his authorized representative.	B. Changes made.
	 4. Prior to participation by individuals in any human research project, the provider shall inform and provide a copy of the IRB or review committee approval to the LHRC. Once the research has been initiated, the provider shall update the LHRC periodically on the status of the individual's participation. B. 4. It seems impractical and unnecessary to require prior approval by the LHRC for each individual seeking participation in research when there is also a requirement for an institutional review board. It is reasonable for the LHRC to be informed of the research and possibly even to approve the research in advance—but not to approve individual participation. 	B. 4. No change.
12 VAC 35-115-140 Complaint and Fair Hearing	■ Change to "informal and formal processes."	■ No change.
New: Part IV Substitute Decision Making	■ At a minimum individuals should be informed of their rights at <u>every</u> step of the process. Human rights advocates should meet with each individual and explain his rights in clear language and offer the opportunity for LHRC review <u>before</u> an AR is appointed.	■ Changes made.
12 VAC 35-115-145 Determination of capacity to give consent and authorization	■ There are no clear guidelines for determining capacity.	 Provisions added to describe what the capacity evaluation should include. Provisions for appeal are provided in 12 VAC 35-
	■ Individuals should be permitted to appeal all capacity evaluations to the LHRC.	115-200.

Section	Comment	Agency Response
12 VAC 35-115-145	A. Paragraph A.1. contradicts the statement in the introduction that "If the capacity	A. No change. Some type of capacity evaluation must
Determination of capacity to give consent and authorization (continued)	. is in doubt, the provider shall obtain " A.1. requires capacity evaluations even for those individuals for whom there is no doubt or controversy about their inability to give informed consent. This is burdensome, unnecessary and expensive for providers. The documentation suggested in A. 3. a. should suffice initially and obviate the need for a formal evaluation.	be on file for each person that has a substitute decision maker.
	A.1 Suggests revisions:	
	Capacity evaluations shall be obtained for all individuals who may lack capacity even if they requested that an authorized representative be designated or to agree to a recommended course of treatment. However, if an individual agrees they may lack capacity and desires to have a family friend or next friend for representation, and there is no known reason to suspect such choice could be injurious to their welfare, their desire will be respected and no capacity evaluation shall be necessary.	A.1. No change.
	A. Suggests revisions:	A. No change.
	A. If the capacity of an individual to consent to treatment, services, or research, or authorize the disclosure of information is in doubt, the provider shall obtain an independent evaluation from a professional who is qualified by expertise, training, education, or credentials and who is not directly involved with the individual or the provider to determine whether the individual has capacity to consent or to authorize the disclosure of information.	
	3. Providers shall determine the need for an evaluation of an individual's capacity to consent or authorize disclosure of information and the need for a substitute decision maker whenever: (i) the individual's condition warrants, or (ii) the individual requests such a review, Once a determination has been made that the individual lacks such capacity, the provider shall have the individual's capacity evaluated at least every six months, and at discharge, except for individuals receiving acute inpatient services.	
	a. If the individual's record indicates that the individual is not expected to obtain or regain capacity, the provider shall have the individual's capacity reevaluated and documented annually that it has reviewed the individual's capacity to make decisions and to determine whether there has been any change in that capacity.	
	b. add in mode of communication that is appropriate and effective for the individual. 4.add Decision-making supports should be person-centered and least restrictive to the liberty of the individual. Consideration should be given to administration of a capacity evaluation that will address ability to provide both general and informed consent.	

Section	Comment	Agency Response
	A. 4. It is not clear from the definition of treatment that "treatment planning" should necessarily require informed consent.	A. 4. Change made in paragraph 4.
	A.5.a. It is not clear who pays for the independent evaluationA.5.a. "If the individual or family member cannot pay for an independent evaluation	A5.a. This provision requires the individual or family to pay for the independent evaluation under the circumstances addressed in the section. Otherwise, the provider pays for the evaluation.
	the individual may request that the LHRC consider the need for an independent evaluation." What happens once the LHRC has considered this.	A.5.a. The regulations establish the process for LHRC reviews in 12 VAC 35-115-200.B.
12 VAC 35-115-146	General Comments:	General Comments:
Authorized representatives	■ Changes require every service provider to have an authorized representative (AR) for every person out of fear of breeching the regulations and increasing their liability.	■ These comments suggest that the regulations will accomplish the opposite of what is intended. This will
	■ An unintended consequence of the regulations could lead to an increasing use of AR to the detriment of consumer decision- making as providers seek to reduce liability.	be addressed in training and consultation.
	■ Expanding the scope of the AR to include all services implies that all individuals with disabilities are incompetent to decide which services they would and would not like to receive.	
	■ Regulations related to authorized representatives, consent, and substitute decision-making are less clear regarding the relationship of the AR to simple consent and informed consent. In the current regulations it is clearer that the involvement of the AR is necessary regarding decisions related to informed consent. In the proposed regs, the AR seems to have a role in any consent. The term "informed consent" no longer appears in the definition of an authorized representative. Concern that this takes away the individual's ability to make all decisions, or makes the process of assessing capacity to consent much more involved.	
	■ Proposes to include "microboard" and "circles of support" in the title and to insert new provisions in sections A. and B . to allow a "microboard duly incorporated under the laws of the Commonwealth or Virginia" or a "circle of support" to act as a substitute decision-maker for an individual who has been determined to lack the capacity for his own decisions.	"Mircroboards" and "circles of support" are not specifically mentioned in these regulations but revisions in the appropriate parts of the regulations support these concepts.
	■ The regulations refer to "authorized representative" but do not clarify who this would be nor that it would inherently include the parent or guardian for an individual under the age of eighteen. Requests clarification.	■ The guardian (AR) of a minor depends on the situation of the minor. This could be a parent or parents, the Department of Social Services or other entity. The AR is determined on a case-by-case basis.
	A . Insert "When it is determinedthe provider shall recognize and obtain consent or authorization for those decisions for which the individual lacks capacity from the following, if one is available "	A. Change made.

Section	Comment	Agency Response
12 VAC 35-115-146 Authorized representatives (continued)	B. The individual's preference for an AR should be paramount. The regulations state that if a next friend is appointed and a relative becomes available, the next friend is removed. We would recommend that the following language be added to the end of the sentence: "unless the individual objects after consultation with the HR Advocate."	B. Change made to 12 VAC 35-146.B.2. to address the comment.
(continued)	B.2. The requirement "within two years prior to the designation" makes the identification of someone who can serve as next friend even more challenging. Programs should be able to identify a volunteer in the same way that guardianship program recruit volunteers who meet the other requirements specified in the regulations.	B.2. A next friend is the only type of AR who is not a relative or designated through an external legal process such as guardian or power or attorney. This provision was the recommendation of the H3R Advisory Committee. No change needed.
	B.2 . For an acute care hospital, it is impractical for the LHRC to approve the appointment of a "next friend." For patients with an average length of stay of 4-5 days, the patient will be discharged before the process can be completed, leaving the patient with no decision-maker. This section should not apply to acute care facilities.	B.2. This is an available option but not a requirement.
	B.2. a. and b . Why is the threshold for qualification to be a next friend much higher than that required for a guardian who would have almost complete authority in the life of the individual.	B.2. a. and b. The provisions for next friend were reviewed, considered and revised based on recommendations from the H3R Advisory Committee. A next friend is the only type of AR who is not a relative
	On the other hand, despite the difficulty of finding appropriate authorized representatives, providers cannot use professional judgment about whether a volunteer, with the approval of the LHRC, might be an appropriate advocate for the individual. As a result there are individuals with <i>no</i> advocate other than the service provider. A community based, trained and interested volunteer would better serve the individual than a for profit guardianship service.	or designated through an external legal process such as guardian or power or attorney. A volunteer or friend, of course, could be an advocate for or support to an individual, but that is different than being the authorized representative with authority to consent to treatment. We support the idea of individuals having many friends or supporters assisting with services or decisions but only certain types of persons qualify to be authorized representatives.
	B.3 Insert the following: In addition to the conditions set forth in subdivision 2 a. The LHRC shall conduct a criminal background check on the nominated next friend; and b. the individual the nominated next friend must have no objection to the proposed next friend being designated as the authorized representative.	B.3. No change.
	C. Employees of the provider should not be appointed as AR and with an exception if the employee is a relative or guardian. Add an exception if the individual has named the employee as attorney-in-fact in a valid power of attorney. Providers should be required to develop policies, approved by the LHRC, to protect any individual in this situation from a conflict of interest.	C. No change.

Section	Comment	Agency Response
12 VAC 35-115-146 Authorized representatives (continued)	E. This is not a viable option in areas without volunteer guardianship programs.	E. Agree that there is a problem identifying substitute decision-makers. Recently, the Department has received funding to expand the public guardianship program, which will be used to address the problem.
	G . The consumer should initiate the re-evaluation to have an AR discontinued and should ask to have the AR rescinded.	G. Change is not needed. This is addressed in 12 VAC 35-115-200.
	G. The last sentence before subsection 1 states that "Powers of attorney and health care agents' powers should cease of their own accord when a clinician has determined that the individual is no longer incapacitated." This is technically inaccurate. Unless the POA is a "springing" POA, the powers do not cease upon the individual's regaining of capacity.	G. Changes made.
	G. Re-write this section to place the burden for the "use of the applicable statutory provisions to remove the authorized representative (see § 37.2 – 1012)" when that authorized representative is the legal guardian, on the Department after the Office of Human Rights has been informed by the provider that capacity has been restored. The Code would allow the guardian to initiate the proceeding to modify or eliminate the guardianship, should they fail to do so and the provider initiates the petition to the Court, it is a virtual certainty that the guardian will remove the individual from the provider's program before the Court acts.	G. No change.
	G . If the individual disagrees with a decision made by an AR, the regulations state that the advocate must be notified and that a petition for LHRC review may be filed. Recommends that the petition shall be filed unless the individual chooses not to do so after consultation with the advocate.	G. No change.
	G.1. Insert "or is clearly acting against the best interests or express preferences of the individual" after the word "serve."	G.1. No change.
	G.2. Add "and expressed preferences" after "interests."	G.2. No change.
	G.3. Insert "a Microboard duly authorized under the laws of the Commonwealth" between "directive" and "a legal guardian.	G.3. No change.
12 VAC 35-115-150	■ Revisions to this section:	■ No change.
General Provisions	A. The parties to any complaint are the individual and the director. Each party can designate someone to represent him. also have anyone else to represent him during resolution of the complaint resolution.	

Section	Comment	Agency Response
12 VAC 35-115-150 General Provisions (continued)	B. Meetings, reviews_and hearings will generally be closed to other people unless the individual making the complaint requests that other people attend or if an open meeting is required by the Virginia Freedom of Information Act. To protect the confidentiality of the individual, meetings, reviews, and hearings are closed to other people except under the following circumstances:	
	(1) When the individual making the complaint requests that the meeting, hearing, or review be open to other people.	
	(2) When an open meeting is required under the Virginia Freedom of Information Act (§2.2-3111 of the Code of Virginia)	
	C -1.—The LHRC and SHRC may conduct a closed hearing to protect the confidentiality of persons who are not a party to the complaint, even if the individual requests an open hearing, but only if a closed meeting is otherwise allowed under the Virginia Freedom of Information Act ('2.2-3700 et seq. § 2.2-3711 of the Code of Virginia).	
	Indicates that the section needs to begin with the principle of conflict resolutionsolve the problem at the earliest stage.	 Inserted "The director shall make every effort to resolve the complaint at the earliest possible stage" in A.
12 VAC 35-115-160	■ The formal and informal complaint process should be monitored or have some	■ No change. The complaint resolution process is
Informal complaint process	oversight by an impartial person appointed by the Department, rather than the provider. This would help to decrease perceptions of conflicts of interest. Indicates that the	monitored by the advocate and the local human rights committee (LHRC).
(repealed section)	process is very lengthy and time consuming. The current complaint process has a better flow.	■ No change.
12 VAC 35-115-170	■ Who fills the directors role if there is a conflict of interest.	■ This would be decided on a case-by- case basis.
Complaint resolution	■ The complaint process time frame should be limited to 5-10 business days.	■ No change.
process	■ Insert "or authorized representative" in the provisions when reference is made to the rights or decision of an individual.	Agree and have made the revision.
	A. Change "may" to "shall" report to the director "or"	A. No change.
	A.3. Suggests inserting the following:	
	The steps in the informal and formal complaint process shall be thoroughly explained to the individual using the mode of communication most effective to the individual, including using alternate formats as needed. The human rights advocate, director, or his designee shall ask the individual if he understands the complaint process and the choice that he has before asking the individual to choose how he wishes to pursue the complaint.	A.3. Changes made.

Section	Comment	Agency Response
12 VAC 35-115-170 Complaint resolution process (continued)	■ D. Step 3-Step 2: The director or his designee shall give the individual and the person the individual has chosen to represent him during the complaint process; his chosen representative a written preliminary decision and, where appropriate, an action plan for resolving the complaint, within 10 working days of receiving the complaint. Along with the action plan, the director or designee shall provide written notice to the individual about the time frame for the individual's response pursuant to Step 3 of this subdivision and a statement the complaint will be closed if the individual does not respond. This decision, the action plan, and the written notice, shall be provided in alternate format if appropriate and explained to the individual in the mode of communication effective for him. E. Step 4 Step 3: If the individual is not satisfied at this step disagrees with the director's preliminary decision or action plan, he can respond to the director within 5-five working days after receiving the director's or the designee's written preliminary decision and action plan. This response shall be in writing or or in alternative form of communication appropriate to the individual's need. If the individual has not responded within five working days the complaint will be closed unless there are emergency or extenuating circumstances beyond the control of the individual which prevent a timely response (e.g., an unexpected hospitalization). F. Step 5-Step 4: The If the individual disagrees with the preliminary decision or action plan the director shall investigate further as appropriate and shall make a final decision and action plan to the individual, the person representing the individual during the complaint process, his chosen representative, and the human rights advocate within 10-five working days after the director received-receives the individual's written response. Along with the action plan, the director shall provide written notice to the individual about the time frame for the individual does not respond th	■ No change. Addressed in other parts of the regulations.

Section	Comment	Agency Response
12 VAC 35-115-170 Complaint resolution process	 A.4. Step 2: Provide examples of "good cause". How is the individual's decision to extend the informal time frame documented. A.5. Step 1: This is not a reasonable timeframe. 	A.4. Step 2 : No change. Providers policies will govern this. Decision is reported to the human rights advocate.
(continued)	A5. Step 1: The Office of Human Rights (OHR) in the Department should not have to be notified every time a person complains. They should be notified only if there is a problem in resolving the complaint or if the individual requests this notification.	A.5. Step 1: No change. A.5. Step 1: No change.
	A. 5. Step 4. The complaint process should indicate that the informal process is followed unless the individual requests the formal process.	A.5. Step 4. Changes made changes to address this comment in 12 VAC 115-150.A.
	■ Also, recommends the following change: Step 4: If the individual disagrees with the preliminary decision or action plan and reports such disagreement to the director in writing within 5 working days after receiving the preliminary decision or action plan, the director shall investigate further	■ Inserted change in Step 4 .
	B. Not clear. Can the director appoint a designee to receive complaints and if not, what happens when the director is unavailable?	B. No change. Provider may appoint designee.
12 VAC-35-180 Local Human Rights	Add "or authorized representative" to each provision referring to rights or decision of an individual."	■ Change made.
Committee hearing and review procedures.	■ Add "emergency or extenuating circumstance" and "alternative format" language in the provisions.	■ No change.
12 VAC 35-115-190 Special procedures for emergency hearings by the LHRC	 Add "or authorized representative" to each provision referring to rights or decision of an individual." Add "alternative format" language in the provisions. The individual's appointed representative should be permitted to participate 	 Changes made. No change. No change is required to address this comment.

Section	Comment	Agency Response
12 VAC 35-115-200 Special procedures for LHRC reviews involving	■ An Individual cannot be forced into treatment in community programs if he continues to refuse treatment, even if the LHRC concludes that the authorized representative was properly appointed.	■ No change needed to address this comment.
consent and authorization.	■ Members of an LHRC are not qualified to make a determination of which evaluation will control when there are two conflicting evaluations. A third independent evaluation should be obtained or a court determination sought.	■ No change.
	2. Suggests the following be added to this provision:	2. No change. The LHRC is not making a clinical
	the LHRC may be requested to decide whether the individual's personal consent is required for any treatment or participation in research which evaluation will control. To facilitate its review, the LHRC shall ask that a physician or licensed clinical psychologist, not employed by the provider, evaluate the individual at the provider's expense, and give a third opinion about his capacity to consent to treatment or authorize information.	determination but is choosing which evaluation controls.
	2.a and 2.b Suggests non-substantive language revisions to this section.	2.a and 2.b No change.
12-VAC-35-115-210 State Human Rights Committee Appeals	■ Require the human rights advocate to explain the process to the individual and to ensure that all communication, submissions, and explanations are provided and accepted in alternative formats in response to individual needs.	■ No change.
procedures	E. Step 4: Retain the 20 day time frame	E. Step 4. No change.
	C. Step 3: Revise as follows:	C. Step 3: No change.
	Within 5 working days of noting or being notified of an appeal, the director shall include a complete record of the LHRC hearing to the SHRC <u>and shall send</u> notification of the appeal to the office of the inspector general.	
	H. Step 7: Suggests inserting:	H. Step 7: No change.
	In the case of appeals involving CSBs and private providers, both-the commissioner and the provider's governing body shall each outline in writing the action or actions they will take in response to the recommendations of the SHRC. They shall also explain any reasons for not carrying out any of the recommended actions. Copies of their responses shall be forwarded to the SHRC, the LHRC, the director, the human rights advocate, and the individual.	The Group Tr. No Gridings.
12 VAC 35-115-220 Variances	■ Recognize the unique dynamics of substance abuse programs in the regulations and not require them to seek variances.	■ No change.
Variatioes	■ Notice of variances should be published in local newspapers. Recommend a new Section I relating to notification.	■ No change.

Section	Comment	Agency Response
12 VAC 35-115-220	F. Add the following:	F. No change.
Variances (continued)	Providers shall develop policies and procedures for monitoring the implementation of any approved variances <u>and documenting the impact of the variance on the individuals being served</u> .	
	F. Suggests adding the following:	
	When a variance is approved, the individuals being served by the provider granted the variance should be informed about the details and specifications of the variance.	F. No change
	G. The process for obtaining a variance should be streamlined rather than adding provisions for a temporary variance.	G. No change.
12 VAC 35-115-230 Provider requirements for	■ Include an expectation for provider and the Department to conduct data analysis of the reported incidents. Compiling numbers of incidents is not sufficient.	■ No change.
reporting to the department	■ More specificity should be required about the deaths that are reportable.	■ No change.
	■ Require the Office of Human Rights of the Department to post details on its website of all substantiated cases of abuse, neglect and exploitation.	■ No change. Information about substantiated cases of abuse and neglect is currently available to the public on request.
	A.1. Require the Department to report to the protection and advocacy agency as required under §51.5-39.12 of the Code of Virginia and to the Office of the Inspector General pursuant to access granted under §37.2-424(4) and(8) of the Code of Virginia. Also add these reporting provisions in B.1. of this section.	A.1. No change.
	A.2. Add: "The director shall also inform the human rights advocates as to whether he has reported the allegation to Department of Social Services, Adult Protective Services, or in the case of a minor child, Child Protective Services."	A.2. No change.
	C. Add "including all actions taken, the rationale for employing seclusion or restraint, and documentation of all other interventions utilized and why they were unsuccessful."	C. No change.
	C.2. Change annual report to monthly report.	C.2. No change.
	■ Proposes changing the annual reporting requirement to reporting on requests when the provider is following a physicians order for restraint.	, and the second
	C.3. Delete C.3. Items preceding it (C.1. and C.2.) mandate that incidents of seclusion and restraint be reported in accordance with 'applicable operating instructions' issued by the Department. The effect of these deletions would be to eliminate the requirement for reporting the duration of protective and medical restraints such as bedrails, safety straps, restraints for medical purposes.	C.3. No change.

Section	Comment	Agency Response
12 VAC 35-115-230 Provider requirements for reporting to the department (continued)	F. Add new part 3. to require the Department to post all provider's data on its website.	F. The information is currently available to the public on request.
12 VAC 35-115-240 Human rights enforcement and sanctions	 Make any sanctions imposed on providers public information. Add a requirement that the Department post information on its website about any sanctions that are imposed on providers. A. Change "may" to "shall". 	 This information is currently available to the public on request. No change. No change. Imposing sanctions is an option not a requirement.
12 VAC 35-115-250 Offices, composition and duties	Insert "or authorized representative" in each instance referring to rights or decision of an individual.	■ Not all situations in these provisions require an authorized representative (AR). The scope of authority of the AR depends on the type of AR and the circumstances.
	 Insert a new provision to ensure that reasonable accommodation is made for the individual's to understand his rights in his primary mode of communication. In several sections certain provider actions and circumstances are required to be reported to the human rights advocate. However, the regulations do not provide any expectation for the advocate to do anything with that information or to even monitor the situation. There should be an expectation of action by the advocate upon receipt of the information. A. 1. The liaison referenced in this provision should be identified ahead of time, not on an ad hoc basis A.6. Concerned that local human rights committees (LHRC's) are unavailable in some geographic areas of the state which makes it difficult for providers to affiliate. Also concerned about lack of resources that are available to some LHRCs which may create hardships in performing duties that are imposed on them. 	 No change. Addressed in other parts of the regulations. No change. Section 12VAC 115-35-250.C explicitly requires the human rights advocate to monitor, investigate, and perform other duties. A.1. No change. Providers generally identify the liaison ahead of time in their policies. A.6. Will address in training and consultation on these regulatory requirements. A.12. No change.
	 A.12. The state should fund clerical support for the LHRC's. Providers should not have to draft minutes for LHRC meetings. A.14. Suggest the following: Post in prominent program locations information about the existence and purpose of the human rights program and the protection and advocacy system. A.17. Add a new paragraph to Section A: "Comply with all requirements set forth in the affiliation agreement with the LHRC as approved by the SHRC" 	A.14. This is addressed in 12VAC35-115-40. A.17. No change. The state human rights committee does not approve this affiliation agreement.

Section	Comment	Agency Response
12 VAC 35-115-250	B.2 Suggests insertion of :	
Offices, composition and duties (continued)	(iii) by reporting all suspected abuse, neglect , and exploitation to the program director. Protecting individuals receiving services from abuse also includes using the minimum force necessary to restrain an individual who is abusing another individual .	B.2. Inserted "neglect and exploitation."
	C.5. Revise to state Whenever appropriate or when requested by the individual or his authorized representative	C.5. No change. C.13. No regulatory requirement
	C.13 . Add requirements that human rights advocates shall be employed in consultation with stakeholders, evaluated annually by the LHRCs they serve and by the consumers and family.	needed. The Department's Office of Human rights always has consumers and frequently has family members on interview panels for its employees.
	C.14 . Add provisions that allow consumers to complain about the human rights advocate and for these complaints to be heard by the State Human Rights Committee (SHRC) and the brought to the attention of the Commissioner of the Department.	C.14. No change.
	D . The SHRC may require multi-site programs to have more than one LHRC affiliate if SHRC determines that additional affiliates are necessary to protect rights. Clarify requirement for programs that have all sites are in the same region or city. What constitutes a region?	D . No change. The SHRC is responsible to determine regions for affiliation purposes (see 12 VAC 35-250.D.2).
	■ Providers with multiple locations should affiliate with an LHRC in each community services board (CSB) area in which they have operations.	■ No change.
	 Suggests several non-substantive language changes to this section to that re-write the description of the LHRC membership. 	No change.
	■ CSBs should provide administrative support to LHRCs.	■ Changes made.
	■ LHRC and SHRC by-laws should set the procedural aspects of the meeting.	■ No change.
	D.2. The provision removes the authority of the LHRC to determine its affiliations and	■ No change.
	transfers this authority to a state employee. Indicates that there are no criteria for determining affiliations.	D.2. No change. This provision does not transfer authority of the LHRC to a state employee. The SHRC
	Concerned about the increase in workload and cost that may result.	is the "supervisor" per se of the LHRC and as such may review any action or activity of the LHRC. This
	The Department's Office of Human Rights should find a way to create more capacity in the human rights system. This is not the responsibility of the LHRC.	provision puts some parameters around such a review if a provider is denied affiliation and also helps to ensure that the rights of individuals will be protected.
	E.5. Add "the respective LHRC, the human rights advocate," after "advice of"	
	E.9. Add "and review" after "development".	E.5. Change made.
	E.17 . Add a requirement that the Department publish the report of human rights activities, etc. on its website and make it available in alternative formats upon request. Also insert in paragraph F.5 . in this section.	E.9. No change.E.17. The annual report is routinely posted on the Department's website and can be made available in

Section	Comment	Agency Response
12 VAC 35-115-250	F. Suggests adding a new provision:	alternative formats, if requested.
Offices, composition and duties	Provide due process rights for members of LHRC in proceedings for removal, assuring the right to counsel, to know the charge, to confront accusers, to present evidence and witnesses on their own behalf, including prior review of	F. Included the by-laws of the SHRC.
(continued)	charges by their own LHRC.	
General Comments	In all places where the regulations state "the individual and his AR as required" add "and the legal guardian of a minor".	■ No change. The scope of authority of an AR is dependent on the type of AR and circumstances.
	■ Organize the regulations in a format that includes "Intent" of standard, "Interpretation," and "Compliance Determination" to create consistency in application of	Will develop a companion document to assist providers to comply with the requirements.
	the regulations for all clients and providers.	■ Changes made in 12 VAC 35-115.J.9.
	■ Indicate that the SHRC appeal is the last level of appeal.	■ Individual's rights to the human rights process do not
	■ The Department's Office of Human Rights, the LHRC and SHRC should be more cognizant of and lend credence to how an individual's disability plays a major role in the complaint process.	change because of his specific type of disability.
	■ The Department should reconsider the organizational structure for abuse and neglect investigations and implement a similar structure to that of the Office of Human Rights in which the human rights advocates report to the State Director of Human Rights in the Central Office who reports directly to the Commissioner. This avoids the conflict of interest that arose when the human rights advocates were directly employed by the facility. This same practice should be in place for abuse and neglect investigatory staff. Recommends that the Office of Human Rights post all substantiated cases of abuse or neglect for all providers, including facilities…"	■ The information is currently available to the public, on request.
	■ Individuals served by, or potentially served by mental health, mental retardation and substance abuse providers may have sensory or physical impairments that require alternative forms of communication such as American Sign Language, Braille, or assistive technology; or may have cognitive impairments that require adjustment in the language used for documents and signs or the way in which messages are imparted. Recommends that "in writing" be accompanied by the phrase, "or in alternative form of communication appropriate to the individual's needs".	■ Added provisions in several areas to address this" in the manner, format and language"
	■ The Office of Human Rights should include private interviews with individuals about services to ascertain the extent to which restrictions occur.	■ The Office of Human Rights conducts interviews with consumers as a means to evaluate services and extent of restrictions.
	■ Include "Microboards" and "Circles of Support" as accepted means of providing assistance for decision-making to individuals with disabilities.	 Change made in various parts of these regulations to support these concepts.

Section	Comment	Agency Response
General Comments (continued)	■ Concerned about the deletions of "These legal rights include, but are not limited to" By deleting "but are not limited to," the agency has closed the door to human rights not specifically articulated in those sections, and has made the sections more restrictive.	■ No change. The deletion of this phrase does not limit any individual rights
	■ Add words " recovery, community integration, consumer direction, and empowerment"throughout the regulations.	Changes made in support of the concepts throughout these regulations.
	 Consumers should be provided training in human rights and in how to file a complaint; annual notification of the rights existence is insufficient. 	■ Provisions inserted to require notification and discussion of the process with consumers at several key points throughout the regulations.
	■ The Department should foster an expectation that services be provided in a person-centered, consumer directed planful manner. Individuals should have respectful and genuine opportunities to discuss and share their strengths, preferences and own goals and ideas about recovery and <u>real</u> community integration.	■ These regulations have been developed to promote and require participation of the individual in all aspects of service delivery.
	■ Ensure that references to consumers are inclusive. They should include brain injury and developmental disabilities because the licensing regulations include these populations.	■ These regulations apply to providers that are licensed, funded or operated by the Department. These regulations apply any individual receiving services from those providers.
	■ Regulations should be written in gender neutral language.	■ The Virginia Registrar of Regulations mandates the style and format of agency regulations that are promulgated in the Commonwealth. The agency must adhere the style guidelines of the Virginia Register.
	Regulations are hard to use. It is difficult to locate certain items.	■ The Department will develop documents to assist in the use and application of the regulations.
	ne Department should study the LHRC model and determine what is the most ent and effective way to ensure oversight including looking at integrating the	■ The Department plans to study the efficiency and effectiveness of the human rights system.
	Office of Human Rights and the Office of Licensing. Regulations should require the posting of the Virginia Freedom of Information Act in all service settings	■ No change. The Virginia Freedom of Information Act does not mandate that providers post this Act. The agency does not impose this standard on providers in these regulations.